IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEMS PRODUCTS LIABILITY LITIGATION

Master File No. 2:12-MD-02327
MDL 2327

THIS DOCUMENT RELATES TO ALL CASES

JOSEPH R. GOODWIN U.S. DISTRICT JUDGE

PLAINTIFFS' RESPONSE IN OPPOSITION TO DEFENDANTS' MOTION FOR PROTECTIVE ORDER RELIEVING DEFENDANTS OF RESPONDING TO PROVISION IN DEFENDANT'S FACT SHEET REQUIRING PRODUCTION OF DEVICE HISTORY RECORDS

Plaintiffs, by counsel, submit their response in opposition to Defendants' Motion for Protective Order Relieving Defendants of Responding to Provision in Defendant's Fact Sheet Requiring Production of Device History Records ("Defendants Motion for Relief").

In support of this opposition, Plaintiffs refer the Court to Ethicon's Response to Plaintiffs' Motion to Clarify and Amend PTO #17 and Plaintiff Leadership Counsel's Position on Defendants' Motion for Sanctions ("Plaintiffs' Motion to Clarify and Amend"), Pretrial Order #180 ("PTO #180"), and the long held legal principle of Goose v. Gander.

BACKGROUND

The Device master records ("DMR") and device history records ("DHR") are two specific types of records required by the U.S. Food and Drug Administration ("FDA") under 21 CFR §820.181/ ISO 13485 §7.5.1.1 and 21 CFR §820.184/ ISO 13485 §7.5.1.1 respectively. The DMR defines the device specific *recipe* for producing a device whereas the DHR shows that the *recipe* used to make the lot/ batch of devices was followed. The DHR demonstrates that device(s) were manufactured in accordance with the DMR (emphasis original).[1]

[1] Ex. 1, Affidavit of Anne Wilson.

According to Anne Wilson, Plaintiff's Biomedical Engineer and Quality Assurance Consultant, both the DMRs and DHRs are required by the FDA in 21 CFR §820.180 and by ISO 13485 §4.2.4 to be kept by medical device manufacturers in order to comply with the Quality System Regulations ("QSR"). These records are required to be immediately accessible for review by the FDA during the course of FDA inspections, which can be conducted upon four days' notice.[2] Provided Defendants are in compliance with these requirements, production of the information requested should not impose any additional burden upon them. Moreover, the information contained in the DHR and the DMR is relevant and necessary information to establish and understand whether Ethicon complied with industry standards for the reporting, trending, and analysis of adverse events and whether complaints and adverse events are caused by design issues or manufacturing issues.

The DHR is defined as "a compilation of records containing the production history of a finished device."[3] "The DHR is used to "facilitate failure investigation and Corrective or Preventative Actions ("CAPA")" as well as to provide traceability information.[4] Manufacturers review the DHR as part of final acceptance activities as required by 21 CFR §820.80(d) to ensure it is correct and complete prior to moving the product to finished goods for permanent implantation into women's bodies.

Adherence to product conformance and performance requirements as found in the DHR are required to be routinely analyzed to provide early warning signs of product related issues that could arise that may require a CAPA be initiated per 21 CFR §820.100 and ISO 13485 §8.4, §8.5.2 and §8.5.3. Based on the requirements described above, retrieving the DHR should be a

[2] *Id.*
[3] *Id.*
[4] *Id.*

routine streamlined and efficient process rather than an arduous process requiring significant resources as stated in Defendants' Motion.

Moreover, each of the women involved with the Ethicon Pelvic Repair Systems Products Liability Litigation have suffered harm from their mesh implant and likely have submitted a formal complaint, known as a Medical Device Report ("MDR"), to the FDA individually or through their treating physician or medical facility. The DHR serves as the basis for investigating such complaints and taking corrective action because it provides a record of any shifts, changes, or variances in the manufacturing process that may result in problems with finished devices. The DHR is the *only* evidence that demonstrates how the lot / batch was built and can demonstrate that the device was manufactured in accordance with specifications per predefined acceptance criteria at the time of release for sale (emphasis added).[5]

The MDR regulation is intended to allow the FDA and manufacturer to identify and monitor adverse events (i.e., deaths, serious injuries and malfunctions). The goal is to detect and correct problems in a timely manner. Thus, to make a MDR determination for each complaint received by the manufacturer, the DHR must be retrieved, reviewed, and a MDR determination made as quickly as possible. Once again, if the retrieval process is as arduous as presented in Defendants' Motion, it is unlikely that Ethicon is in compliance with industry standards and regulations concerning the storage and retrieval of the same information requested by the Plaintiffs. Given that Ethicon's own internal documents document non-compliance with record retention in the past, this is not surprising.[6]

ARGUMENT

A. The Parties Agreed to the Form and Content of the DFS.

[5] *Id.*
[6] Ex. 12, ETH.MESH.00332854.

Borrowing from Ethicon's own prior arguments, Pretrial Order No. 17 ("PTO #17") was entered on October 4, 2012, and describes the discovery obligations applicable to every party in the MDL. PTO #17, resulted from the discovery planning conferences directed by the Court pursuant to Rule 26(f) of the Federal Rules of Civil Procedure. This alternative to the initial discovery disclosures set forth in Rule 26(a)(1), and to written discovery requests by the parties, was negotiated and agreed to by counsel for both parties. The Court accepted the parties' agreement by the entry of PTO #17 which modifies the parties' initial discovery obligations under Rule 26(a)(1) and tailors those obligations to fit the complexity, volume and exigencies of this products liability litigation. Ethicon now wishes to be relieved from responding to one of the provisions, specifically, the provision related to DHRs, absent a showing of need on the part of a particular Plaintiff.[7] This Court previously denied Plaintiff's request to modify PTO #17 based in part on its reluctance to disturb such an agreement that was entered into willingly by each party.[8]

The parties spent considerable time negotiating the form of the Defendant's Fact Sheet ("DFS") which was meant to serve as the initial plaintiff specific discovery of defendants. The parties agreed that production of the DHR would be accepted in lieu of other more extensive productions relating to the quality control process that takes place just prior to the product being distributed for implantation into women all around the world.

There is no question that complex litigation is inherently burdensome for all involved, but that does not mean the Defendants can avoid producing documents that are within their custody and control. Because Plaintiffs have the burden of proof, the less information Defendants produce, the more difficult it becomes for Plaintiffs to meet their burden to the Court and the

[7] *See* Defendants' Motion at1-2.
[8] *See* Pretrial Order #180.

jury. Numerous hours have already been spent by Plaintiffs' counsel determining what information would be necessary to support the claims asserted in their Master Complaint. Even more hours have been spent trying to piece together the manufacturing history due to the fact that Defendants have been allowed a "rolling" discovery where documents have been produced in piece meal fashion. This has further been complicated by the number of documents already known to have been lost or destroyed.[9] The entire purpose of discovery is to find out what defendant has in its possession, custody and control; to suggest that plaintiffs must assume the burden of figuring out and then proving that such documents exist prior to production is at fundamental odds with the purpose of discovery in the federal courts. Consequently, requiring the Plaintiffs to "show a need" in a particular case before such production is warranted would only be another way of rewarding the Defendants for "hiding the ball" from Plaintiffs.

B. The DHRs will be used by Plaintiffs' Experts in forming and supporting their opinions as well as for cross examination of Defendants' Experts regarding both the Manufacturing and Design Defect claims.

Plaintiffs in this MDL have tailored their discovery requests to obtain documents relevant to each of their claims, including their claims for Manufacturing and Design Defects. The information contained in the DHR productions is highly relevant to both of these claims.

Defendants do not dispute the relevance of the DHRs; however, they argue that the discovery sought is too burdensome and have asked that this Court require Plaintiffs to justify a specific need for it before they must produce the requested documents. They base this argument in part on the fact that Plaintiffs have not used the DHRs at any trial or deposition in connection with an individual Plaintiff's case to date. The Court should not be swayed by such an argument.

[9] Hundreds of pounds worth of boxes from Medscand Medical A.B., the original manufacturer of the TVT product, were destroyed by Ethicon despite the fact that a litigation hold was in place at the time. *See*, Ex. 2, Deposition Transcript of Laura Angelini 9/16/2013 at 53:13-56:16. Also, as indicated in the declaration of Mary Carmel Lowe, a large number of documents were destroyed in the Secur-Archiv records storage fire in Lausanne, Switzerland that began on 9/25/2009.

Defendants argue that the discovery sought by the DFS provision creates a disproportional burden and is unduly costly. However, information necessary to enable a party to prepare his case or to facilitate proof at the trial or to expedite progress of the trial, should be produced even though there may be an inconvenience or burden on the party producing them if the benefit to the litigation outweighs the burdens of discovery. *Hanover Shoe, Inc. v. United Shoe Machinery Corp.*, 207 F.Supp. 407, 409 (M.D.Pa.1962). *See also, U.S. v. American Optical Co.*, 39 F.R.D. 580, 587 (N.D.Cal.1966) ("the fact that the production of documents may involve inconvenience and expense is not alone sufficient reason for refusing discovery which is otherwise appropriate."); *Rockaway Pix Theatre, Inc. v. Metro-Goldwyn-Mayer, Inc.*, 36 F.R.D. 15, 17 (E.D.N.Y.1964) ("all sources of information should be made available regardless of expense...and the mere fact that production would be onerous or inconvenient is not, per se, grounds for denial of a Rule 34 motion.").

The kinds of documents typically contained in the DHR are the type only an expert would rely on. Moreover, a lay person would not necessarily understand or even be able to read the documents because most of them are produced in a foreign language. As stated above, the DHR contains the production history for a particular batch of finished devices. Federal regulations require that procedures are established and maintained to insure that the DHRs for each lot are properly created and routinely analyzed to provide early warning signs of product related issues that could arise and cause harm to patients implanted with a particular device. The information contained in this production is the only information available to an individual plaintiff with respect to whether or not the device implanted in her was manufactured in accordance with the DMR.

By way of example, in *Ramirez v. Reyes, et al*.,[10] a case that is currently set for trial in Bexar County, TX in April 2016, the plaintiff was implanted with a TVT Obturator ("TVT-O") device, from lot number 3405428 ("Lot 428"). According to the DHR documents (produced in response to the DFS for this individual plaintiff) it was learned that Lot 428 suffered from multiple problems beginning with its production and stretching to the present in the form of adverse event reports. Problems documented with Lot 428 include the return of the products, complaints of particle loss and brittle mesh,[11] published estimates of 10% particle loss,[12] and/or the associated threat by French regulatory agents to suspend sales for excessive particle loss.[13] Particle loss is a significant part of Plaintiff's Manufacturing and Design Defect claims in this lawsuit. Additionally, Ethicon's witnesses have admitted in deposition that each particle will produce an inflammatory response and granuloma formation in the pelvis,[14] as well as potential bladder calculi.[15] As such, Plaintiff's Experts have reviewed and relied in part on the information obtained from the DHR to support their finding that defects with the TVT-O device caused the plaintiff's injuries.[16] These same documents, and the information they provide, will also be used to cross examine Defense Experts that try to refute the same.

There can be no more integral evidence to a medical device product liability lawsuit than the specific production history of the device. Without the production already agreed to by the Defendants, Plaintiffs have no way of discovering, as in *Ramirez*, whether there were problems in the manufacturing process for particular lots or groups of devices.

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[10] Case No. 2012-CI-18690
[11] Ex. 3, ETH.MESH.00863391; *see also*, Ex. 4, Deposition of Thomas Barbolt, 8/15/2013, at page 368.
[12] Ex. 5, JL Pariente, An Independent Biomechanical Evaluation of Commercially Available Suburethral Slings, Issues in Women's Health, ETH.MESH.01221055.
[13] Ex. 6, ETH.MESH.03358217; *see also*, Ex. 4, Deposition of Thomas Barbolt, 8/15/2013, at page 413.
[14] Ex. 4, Deposition of Thomas Barbolt, 8/15/2013, at 394-395, 422; *see also*, Ex. 7, Deposition of Brigitte Hellhammer, 9/11/2013, at page 356.
[15] Ex. 8, ETH.MESH.00844341, *see also*, Ex. 4, Deposition of Thomas Barbolt, 8/15/2013, at 456.
[16] Ex. 9, Expert Report of Michael Thomas Margolis, M.D., 4/24/2015, at pgs. 4 and 7; Ex. 10, Expert Report of Bruce Rosenzweig, M.D., 4/24/2015, at pg. 12.

C. Defendants Should not be Allowed to Shift Costs to the Plaintiffs.

Defendants have asked this Court to shift the costs involved in producing the documents related to the DHRs to Plaintiffs. However, this is not the first time Defendants have asked this Court to shift the cost of discovery to the Plaintiffs.[17] As this Court is aware, Johnson & Johnson earned $67.2 billion in worldwide sales in 2012, an increase of 3.4 percent from 2011. It is a member of the Fortune 100." Moreover, "[w]ith over 27.4 billion in worldwide sales in 2012, [J&J's] [] Medical Devices and Diagnostics (MD&D) business is the largest in the world."[18] Defendants are well aware of the fact that litigation in general, including the burden and expense of producing such documents requested by the Plaintiffs, is a cost of doing business. Consequently, Ethicon has become one of the world's largest, multibillion dollar pharmaceutical and medical device manufacturers as a result of that business.

Defendants have not demonstrated that the documents requested are "inaccessible," just that retrieval has been complicated by the manner in which the documents are stored, which is inconsistent with the prior testimony of Colin Yuill, Ethicon's Corporate representative for Quality Assurance. When questioned about the manufacturing process and the purpose of the batch history records, Mr. Yuill testified that the last step in the process was to place the information into the "JDE database for easy retrieval of information" and confirmed that all batch records are kept in a database. [19] As such, their production should not be onerous or costly. Nevertheless, Federal Courts have consistently held that, "an unwieldy record-keeping system, which requires heavy expenditures in money and time to produce relevant records, is simply not an adequate excuse to frustrate discovery," especially when such discovery has been

[17] *See*, Pretrial Order #68 in 2:12-MD-2327, 9/18/2013, *see also*, Pretrial Order # 24 in 2:12-md-2325, 10/30/12.
[18] Johnson & Johnson Fact Sheet [http://www.jnj.com/sites/default/files/pdf/Johnson-Johnson_Factsheet_May%202013.pdf] .
[19] *See* Ex. 11, Deposition Transcript of Colin Yuill 11/29/2011, at 56:7-16.

specifically agreed to by Ethicon in the negotiations that led to PTO 17, and when such discovery is narrowly tailored to generate relevant and material information specific to Plaintiffs' claims. *See Rhone-Poulenc Rorer, Inc. v. Home Indemnity Company,* 1991 WL 111040 (E.D. Pa. 1991) (*citing In re Richardson–Merrell,* 97 F.R.D. 481, 483 (S.D. Ohio 1983)); *Dunn v. Midwestern Indemnity,* 88 F.R.D. 191, 197–98 (S.D. Ohio 1980); *Kozlowski v. Sears, Roebuck & Co.,* 73 F.R.D. 73, 76 (D.Mass. 1976); 4 A. Moore's Federal Practice §§ 34–19[2] at 34–106 2d Ed.1981). *See also Automated Merchandising Systems, Inc. v. Crane Co.,* __ F.R.D. __; 2011 WL 5025907 at 9 (N.D. W. Va. 2011); and *Cochran v. Caldera Medical, Inc*., 2014 WL 1608664 (E.D. Pa. 2014). Additionally, even if one ignores the testimony of their corporate representative, and credits the affidavit presented by the Defendant in support of its motion here, Defendant's own document storage practices, not the information requested is the problem. Plaintiffs should not be punished for that fact.

Regardless of whether or not Defendants anticipated that the MDL Bellwether pools would initially be limited to 20 plaintiffs, it was always understood that, absent a comprehensive resolution plan to resolve all of these cases, the cases would need to be worked up and remanded to their original jurisdiction for trial. Given Ethicon's choice to pursue the litigation track,, it should not come as a surprise to them that they will have to marshal the resources and produce the documents that critical to support the Plaintiffs' product defect claims. Defendants have been aware since the beginning of the number of cases that could potentially be brought against them. As stated above, a number of the manufacturing batch records in Wave 1 are no longer available due to being lost or destroyed. It is very likely that Wave 2 (as well as any subsequent Waves) will be similar, making the burden much less than Defendants are claiming.

CONCLUSION

For the reasons set forth herein, the Court should deny "Defendants' Motion for Protective Order Relieving Defendants of Responding to Provision in Defendant's Fact Sheet Requiring Production of Device History Records."

Dated: December 9, 2015.

Respectfully submitted,

/s/ D. Renee Baggett
Bryan F. Aylstock, Esq.
Renee Baggett, Esq.
Aylstock, Witkin, Kreis and Overholtz, PLC
17 East Main Street, Suite 200
Pensacola, Florida 32563
(850) 202-1010
(850) 916-7449 (fax)
E-mail: rbaggett@awkolaw.com

CERTIFICATE OF SERVICE

I hereby certify that on December 9, 2015, I electronically filed the foregoing document with the Clerk of the court using CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

/s/ D. Renee Baggett
D. Renee Baggett, Esq.
Aylstock, Witkin, Kreis and Overholtz, PLC
17 E. Main Street, Suite 200
Pensacola, FL 32563
850-202-1010
850-916-7449
rbaggett@awkolaw.com